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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/502,347	07/14/2005	Ali Rezai	12637/58	6087

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EXAMINER	
FLORY, CHRISTOPHER A	

ART UNIT	PAPER NUMBER
3762	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/502,347	REZAI ET AL.	
	Examiner	Art Unit	
	CHRISTOPHER A. FLORY	3762	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *29 January 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-3,5,7-16,18,19,21-25 and 27-31* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-3,5,7-16,18,19,21-25 and 27-31* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Continued Examination Under 37 CFR 1.114

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 29 January 2008 has been entered.

Response to Arguments

2. Applicant's arguments with respect to claims 1-3, 5, 7-16, 18, 19, 21-25 and 27-31 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-3, 5, 7-13, 15, 19, 21-25 and 27-31 are rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval (US 6,178,349, hereinafter Kieval'349). It is noted that Testerman et al. (US 5,344,438, hereinafter Testerman'438) is incorporated by reference (col. 5, lines 52-55) and also relied upon in this rejection. Citations to

Kieval'349 will be made in plain text, while citations to Testerman'438 will be made in ***bold italic text***.

Regarding claims 1, 13, 14, 18, 19, 22, 23 and 25, Kieval'349 discloses a delivery device (Kieval'349: Fig. 1) for stimulating a ganglion of the sympathetic nervous system (Kieval'349: Fig. 2; column 4, lines 14-45) comprising a first and second series of flexibly connected delivery contacts (Kieval'349: Fig. 1, first series comprises electrode and reservoir system 92, second series system 94; column 5, lines 40-45. ***Testerman'438: Fig. 3, any of delivery contacts 64-86 can be set up in series (col. 3, lines 35-57)***). Regarding Kieval'349, it is noted that the electrode 116 and reservoir 114 of Fig. 2 are both delivery ports, and that the leading contact (114) is engagably associated with the trailing delivery contact (116) in an operative position (column 6, lines 22-24 and 54-63; column 7, lines 31-34). Regarding Testerman'438, it is noted that any of ***contacts 62-86 in Fig. 3*** can be considered the leading and trailing contacts, all of which are engagably associated in both the first and second series.

Further regarding claims 1, 14, 19 and 23 it is noted that the terms "delivery contacts," "probe," "terminal member" and "clamping members" all substantially define the same or substantially similar structures, each of which is clearly anticipated by Kieval'349.

Further regarding claim 1, Testerman'438 discloses a third series between and connected to both the first and second series (***Fig. 3, contacts 82-86; column 3, lines 35-57***).

Still further regarding claim 1, Kieval'349 discloses a first, second and third series of contacts each having a respective diameter, but does not expressly disclose that the third diameter is greater than the first or second diameters. It would have been an obvious matter of design choice to one of ordinary skill in the art at the time of the invention to modify the system as taught by Kieval'349 with the larger third diameter, because Applicant has not disclosed that a third diameter larger than either of the first or second diameter provides an advantage, is used for a particular purpose, or solves a stated problem. One of ordinary skill in the art, furthermore, would have expected Applicant's invention to perform equally well with the nerve cuff as taught by Kieval'349, because it provides a means for securing the nerve cuff around a nerve in electrical contact therewith, and since it appears to be an arbitrary design consideration which fails to patentably distinguish the instant application over Kieval'349 . Therefore, it would have been an obvious matter of design choice to modify the system of Kieval'349 to obtain the invention as specified in the claim(s).

Regarding claims 2, 3 and 11, the electrode/reservoir configuration of Kieval'349 can be considered concave or convex depending on whether you refer to the inside or outside portion of the cuff. Alternatively, it can be seen that the electrode plate on the inside of the cuff is concave, whereas the electrode material that extends around the flat edges of the cuff (Fig. 2 under reference 116) holds a generally convex shape. Additionally, the multi-electrode embodiments, such as the one illustrated by Testerman'438 also show a first series (***Fig. 3, electrodes 62-66***) arranged in a

concave configuration relative to the centerline, and a second series (***Fig. 3, electrodes 72-76***) in a convex configuration relative to the centerline.

Regarding claim 5, Kieval'349 discloses the first, second and third series each comprising four delivery contacts, wherein one can consider the reservoir to be a first contact, and the three series electrodes (shown as the disclosed embodiment of ***Testerman'438, Fig. 3***) as the remaining three electrodes to make a total of four contacts. Alternatively, Kieval'349 discloses the use of a plurality of electrodes (column 5, lines 40-45), but does not expressly disclose 4 electrodes. It would have been obvious to one having ordinary skill in the art at the time of the invention to include 4 contacts, since it has been held that mere duplication of essential working parts of a device involves only routine skill in the art. *St. Regis Paper Co. v. Bemis Co.*, 193 USPQ 8.

Regarding claims 7 and 8, Kieval'349 discloses that the delivery contacts can be either electrodes or drug ports (ABSTRACT).

Regarding claim 9, and further regarding claim 14, the device disclosed in Kieval'349 is capable of being inserted into a ganglion.

Regarding claim 10, Kieval'349 discloses delivery contacts having a trapezoidal configuration (Figs. 3 and 4, wherein the electrode and reservoir are each trapezoidal). Alternatively, Testerman'438 discloses trapezoidal contacts (***column 2, lines 39-45***).

Regarding claim 12, and further regarding claims 14, 19 and 23, Kieval'349 discloses an axially elongated shaft (Fig. 1, leads 96 & 98). The shaft is considered slidably engagable with the device because the suture means (Fig. 2, left of reference

94) is slidable along the lead to secure the cuff. Additionally, the cuff is slidable or positionable along the nerve. It is further noted that the disclosed leads are inherently slidably engaged with the nerve cuffs, as the lead housing must be inserted with the nerve cuff in the construction of the device.

Regarding claims 15, 21 and 24, the suture element shown in Figure 2 of Kieval'349 (***element 140 of Testerman'438***) is considered to be a detachable limit stop.

Regarding claim 27, Kieval'349 discloses clamping members hingedly connected to each other. The nerve cuff 112 shown in Fig. 2 is disclosed as being flexibly deformable, wherein the flat front edges are temporarily drawn apart and placed around the nerve, wherein upon release of tension the cuff returns to its original conformation and holds the cuff substantially in contact with the nerve without need for sutures. Therefore, if one considers the front flat edges to be the clamping members, they are hingedly connected due to the flexible nature and intended application of the nerve cuff. Alternatively, each nerve cuff 92 and 94 shown in Figure 1 can be considered a clamping member, those hingedly connected by element 100.

Regarding claims 28-31, Kieval'349 discloses a method of stimulating a ganglion comprising encasing a delivery device around a portion of a sympathetic ganglion and providing a stimulation signal to the ganglion while maintaining an ovoid shape (column 4, lines 14-45; column 5, lines 2-26), wherein a semi-circular cuff is considered to be substantially ovoid.

Further regarding claims 30 and 31, it is noted that the stimulator and shaft are considered slidably engagable for the reasons set forth above in regards to claim 12

5. Claims 14, 16 and 18 rejected under 35 U.S.C. 103(a) as being unpatentable over Kieval'349, or alternatively over Kieval'349 in view of Levin et al. (US 205/0234523, hereinafter Levin'523) or in view of Shafer (US 2005/0075701, hereinafter Shafer'701).

Regarding claims 14 and 18, Kieval'349 discloses a delivery device (Kieval'349: Fig. 1) for stimulating a ganglion of the sympathetic nervous system (Kieval'349: Fig. 2; column 4, lines 14-45) comprising a first and second series of flexibly connected delivery contacts (Kieval'349: Fig. 1, first series comprises electrode and reservoir system 92, second series system 94; column 5, lines 40-45. ***Testerman'438: Fig. 3, any of delivery contacts 64-86 can be set up in series (col. 3, lines 35-57)***). Regarding Kieval'349, it is noted that the electrode 116 and reservoir 114 of Fig. 2 are both delivery ports, and that the leading contact (114) is engagably associated with the trailing delivery contact (116) in an operative position (column 6, lines 22-24 and 54-63; column 7, lines 31-34). Regarding Testerman'438, it is noted that any of ***contacts 62-86 in Fig. 3*** can be considered the leading and trailing contacts, all of which are engagably associated in both the first and second series.

Further regarding claim 14, it is noted that the terms "delivery contacts," "probe," "terminal member" and "clamping members" all substantially define the same or substantially similar structures, each of which is clearly anticipated by Kieval'349.

Still further regarding claim 14, the device disclosed in Kieval'349 is capable of being inserted into a ganglion.

Still further regarding claim 14, Kieval'349 discloses an axially elongated shaft (Fig. 1, leads 96 & 98). The shaft is considered slidably engagable with the device

because the suture means (Fig. 2, left of reference 94) is slidable along the lead to secure the cuff. Additionally, the cuff is slidable or positionable along the nerve. It is further noted that the disclosed leads are inherently slidably engaged with the nerve cuffs, as the lead housing must be inserted with the nerve cuff in the construction of the device.

Regarding claim 16, and still further regarding claim 14, the first and second probes disclosed in Kieval'349 are each considered to define a first and second prong for the same reasoning provided regarding claim 27. Alternatively, within each probe as seen in Fig. 2, the leading edges (e.g. element 16 as well as the opposing edge) can be considered a prong capable of insertion into a ganglion, thereby making a first probe having two prongs and a second probe having two prongs. Alternatively, in the same problem solving area, Levin'523 teaches electrodes with a prong end, such as a barb or screw, to facilitate insertion and permanent placement of the electrode in the targeted tissue (paragraphs [92], [111]). In the same field of endeavor, Shafer'701 teaches tined electrode leads wherein the tines facilitate attachment of the lead to the desired structure and to position the electrodes against the targeted tissue (paragraph [84]). Alternatively, pronged, or tined, or variously anchorable electrodes are well known in the art, e.g. in applications with ventricular placement of a screw-in lead, for the purpose of securing the electrode to the targeted area as well as facilitating electrical stimulation thereof by providing deeper tissue penetration and a higher surface area for stimulation current to be delivered.

Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Christopher A. Flory whose telephone number is (571) 272-6820. The examiner can normally be reached on M - F 8:30 a.m. to 5:00 p.m..

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Angela Sykes can be reached on (571) 272-4955. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Christopher A. Flory

19 March 2008

/George Manuel/
Primary Examiner